DEC 17 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
cPSA Assay for Bayer ADVIA® Integrated Modular System (IMS)™

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K022288

1. Intended Use

The *Bayer ADVIA® IMS* cPSA assay is an *in vitro* diagnostic device intended to quantitatively measure complexed prostate specific antigen (cPSA) in human serum. This assay is indicated for the measurement of serum complexed PSA as an aid in management (monitoring) of prostate cancer patients. Complexed PSA values obtained using the Bayer ADVIA IMS assay method must be interpreted in conjunction with all other available clinical and laboratory data before a medical decision is determined.

Prostate Specific Antigen (PSA) is a secretory product of the epithelial cells of human prostatic tissue, whether normal, benign, or malignant. The tissue specificity of PSA makes it a sensitive and specific tumor marker as an aid in management (monitoring) prostate cancer patients and disease progression following surgery or other therapies. PSA in serum exists in several forms including free, uncomplexed PSA and PSA complexed to several protease inhibitors including α-2-macroglobulin, α-1-antichymotrypsin (ACT), and α-1-antitrypsin. It should be noted that there are no existing commercial methods that can recognize PSA bound to α-2-macroglobulin. However, it has been demonstrated that the proportion of PSA complexed with ACT increases as a function of the total PSA concentration, and that the majority of immunoreactive PSA in cancer patients is in complex with ACT. The Bayer cPSA Assay uses a monoclonal antibody for capture which recognizes both free and complexed PSA, but which, when bound to free PSA, precludes the binding of other antibodies specific for the free form of PSA. The inclusion of a second, unlabelled monoclonal antibody which is specific for free PSA prevents the binding of free PSA in the cPSA assay and allows measurement of only PSA which is complexed with ACT. cPSA can be used as a single test alternative to free and total PSA in management of patients with CaP.

2. Predicate Device

Product Name	Reagent Part #	Calibrator Part #
Immuno 1 cPSA Assay	T01-3982-51	T03-3983-01

3. Device / Method

Product Name	Reagent Part # / BAN Number	Calibrator Part # / BAN Number
ADVIA IMS cPSA Assay	B42-4114-42 / 00955033 (100 tests) 00923573 (250 tests)	B43-4115-01 / 06176311

Imprecision

Within-run and total imprecision were evaluated by testing six calibrator levels and commercial controls. % CV was calculated based on all replicates using one calibration curve. Ten runs were performed: two runs/day for four days, and two more runs-one run/day. Total number of replicates = 40

ADVIA IMS	
Level (ng/mL)	Total CV(%)
3.47	3.0
15.55	3.4
77.21	3.8

Immuno 1	
Level (ng/mL)	Total CV(%)
1.0	2.5
10	2.5
50	2.1

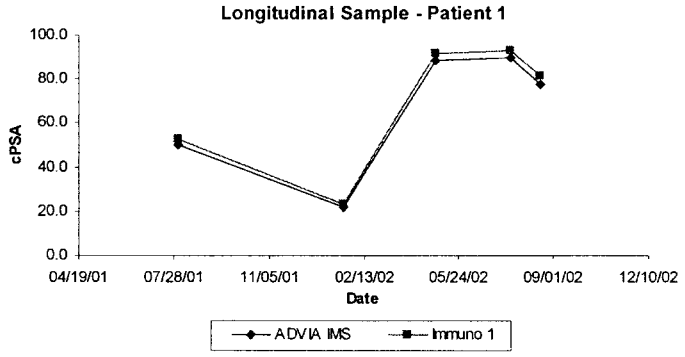
Correlation (Y= ADVIA IMS, X=comparison system)

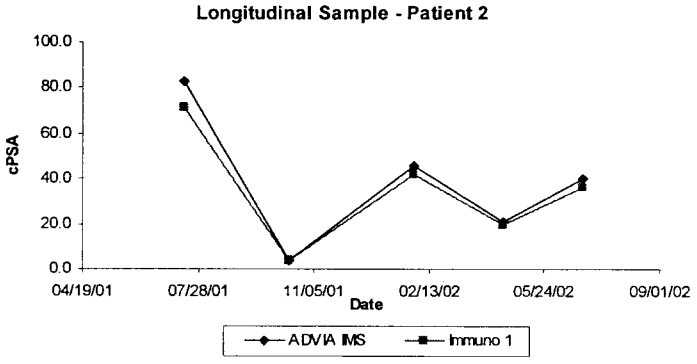
Correlation study was performed using forty five (45) serum samples (0.03 to 69.69 ng/mL)

Specimen type	Comparison System (X)	N	Regression Equation	Syx (ng/mL)	R	Sample Range (ng/mL)
Serum	Immuno 1	98	0.988 * X – 0.191	0.706	0.999	0.14-86.28
Serum	Immuno 1	45	1.004 * X - 0.336	0.566	0.999	0.03-69.69

Serial Monitoring

Two examples of serial patient monitoring studies using Bayer ADVIA IMS assay results in comparison to results obtained for another marketed device are shown in the following figures.





Interfering Substances

Serum pool with cPSA concentration of about 3.7 ng/mL was spiked with hemoglobin, triglyceride, bilirubin, albumin, immunoglobulins, PAP, kallikrein, and drug pools (up to two times lethal dose) and then assayed for cPSA. In all cases the observed recovery bias was found to be of no clinical significance.

Interfering Substance	Interfering Substance Concentration mg/dL	cPSA Concentration (ng/mL)	Effect (% change)
Hemoglobin	1000	1.92	1.5
Lipids (Triglycerides)	1000	3.46	-0.5
Bilirubin	25	3.67	-1.1
IgG	6.0	2.82	-2.8
Albumin	6.5	2.86	2.0

Cross-Reactant	Cross-Reactant Concentration (µg/mL)	cPSA Concentration (ng/mL)	Effect (% change)
PAP	1.0	3.63	-0.012
Kallikrein (plasma)	1.0	3.63	-0.001
Kallikrein (urine)	1.0	2.17	-0.012
Vincristine Sulfate	13.5	2.06	-0.7
Vinblastine	5.11	2.06	-0.7
Mitomycin C	73	3.28	1.8
Tamoxifen - Free	60	2.06	-0.7
Tamoxifen - Citrate	60	2.06	-0.7
Etoposide	415	2.06	-0.7
5-Fluorouracil	1600	3.42	5.8
Cyclophosphamide Monohydrate	800	3.28	1.8
Doxorubicin HCl	51.8	3.28	1.8
Diethylstibestrol	23	2.06	-0.7
Methotrexate	450	3.08	-2.6
Cis-Platinum	173	2.06	-0.7
Megestrol Acetate	243	3.22	1.8
Lupron	15		

Recovery

Recovery of the cPSA dilution in the range of 0.01 to 4.0 ng/mL was evaluated. Recovery ranged from 97 to 106%.

Sample #1

Expected , ng/mL	Observed, ng/mL	Recovery, %
3.61	3.61	100
2.74	2.80	102
1.88	1.83	97
1.01	1.00	99
0.14	0.14	100
	Mean	100

Sample #2

Expected , ng/mL	Observed, ng/mL	Recovery, %
3.86	3.86	100
2.93	3.01	103
2.00	2.02	101
1.07	1.06	99
0.14	0.14	100
	Mean	101

Sample #3

Expected , ng/mL	Observed, ng/mL	Recovery, %
4.09	4.09	100
3.07	3.06	100
2.05	2.01	98
1.03	1.03	100
0.01	0.01	100
	Mean	100

Sample #4

Expected , ng/mL	Observed, ng/mL	Recovery, %
3.95	3.95	100
2.98	3.02	101
2.00	2.09	105
1.03	1.09	106
0.05	0.05	100
	Mean	102

Analytical Range
0.01 – 100 ng/mL

Minimum Detectable Concentration

ADVIA IMS (ng/mL)	Immuno 1 (ng/mL)
0.01	0.02

4. Conclusion

Performance of the ADVIA IMS cPSA Assay on a *Bayer ADVIA*® IMS™ is equivalent to the performance of the cPSA Assay on the predicate device (Immuno 1) and is within proposed specifications. No safety and effectiveness issues have been raised.

K. Edds
Director Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

12/04/02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 17 2002

Kenneth T. Edds, Ph.D.
Regulatory Affairs Manager
Bayer Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591

Re: k022288
Trade/Device Name: cPSA (Complexed Prostate Specific Antigen) Assay for the ADVIA® IMS™
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: LTJ; JIS
Dated: December 5, 2002
Received: December 6, 2002

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K022288

Device Name: cPSA (Complexed Prostate Specific Antigen) Assay for the ADVIA® IMS™

Indications for Use:

The *Bayer ADVIA® IMS* cPSA assay is an *in vitro* diagnostic device intended to quantitatively measure complexed prostate specific antigen (cPSA) in human serum. This assay is indicated for the measurement of serum complexed PSA as an aid in management (monitoring) of prostate cancer patients. cPSA values obtained using the *Bayer* ADVIA IMS assay method must be interpreted in conjunction with all other available clinical and laboratory data before a medical decision is determined.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

J Pleus for L. Bautista

Sign-Off)

Clinical Laboratory Devices

Number K022288